



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

OCT 30 2000

Joe Vidal, Director  
EFAsense Ltd.  
5 Crescent Hill Drive, South  
Brampton, Ontario L6S 2P2  
Canada

Rec'd 1/15/2000  
yb

Dear Mr. Vidal:

This is in response to your letter of September 27, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that EFAsense, is making the following claim, for the product **EFAsense Borage Oil**:

"It also supports the healthy functioning of the cardiovascular system including normal blood clotting and circulation."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

f/t:HFS-811:afp:10/19/00:docname72821:disc1

# EFAsense™

September 27, 2000

Food and Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, CD 20204

Dear Sir or Madam,

Notice is hereby given pursuant to the requirement of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that EFAsense Ltd., 5 Crescent Hill Drive South, Brampton, ON L6S 2P2 within the past 30 days commenced marketing dietary supplements bearing the following statement(s) on the label and/or in the labeling:

**Text of Claim:** This blend of borage, fish and flax oils supplies a healthy balance of essential fatty acids. GLA, LA, ALA, DHA and EPA are important factors in the optimal functioning of all cells of the body. They help support healthy skin, cardiovascular, joint and immune system function. This EFA blend also supports normal brain, nerve and eye function. The Multi-EFA is a convenient way to supplement your diet with essential fatty acids. People with low fat diets, or diets high in saturated and hydrogenated fats or trans fatty acids may not consume sufficient EFAs in their diet.

**Name of ingredient that is subject of claim:** Borage Seed Oil, Fish Oil, Flax Seed Oil

**Name of supplement (including brand name):** EFAsense Multi-EFA 1200 mg Softgel

**Text of Claim:** Borage oil is nature's best source of GLA, an essential fatty acid. GLA is a precursor to series 1 prostaglandins which maintain normal body function. GLA is beneficial in the healthy functioning of the nervous system, cell membranes, skin, synovial membranes, connective tissue and joints. It also supports the healthy functioning of the cardiovascular system including normal blood clotting and circulation. Supplementation with GLA may diminish the common symptoms of PMS such as breast tenderness, bloating, minor mood changes and skin problems. Prostaglandins play an important role in maintaining hormonal balance, which can fluctuate at different stages in a woman's life.

**Name of ingredient that is subject of claim:** Borage Seed Oil

**Name of supplement (including brand name):** EFAsense Borage Oil 1000 mg Softgel

**Text of Claim:** A beneficial blend of EFAs and synergistic herbs. PMS Formula is a synergistic blend of essential fatty acids from borage and flax oils along with bioflavonoids, cramp bark, vitamin B6 and vitamin E. It helps maintain hormonal balance and may alleviate minor PMS symptoms such as cramping, breast tenderness, minor mood changes, headaches, bloating and skin problems. Cramp bark has a traditional history of use in treating PMS cramping. Vitamin B6 helps avoid PMS by assisting the body in maintaining normal estrogen levels. Bioflavonoids promote good health through their antioxidant and protective effects on cells.

**Name of ingredient that is subject of claim:** Borage Seed Oil, Flax Seed Oil, Cramp Bark Extract, Bioflavonoids, Vitamin B6, Vitamin E

**Name of supplement (including brand name):** EFAsense PMS Formula 908 mg Softgel